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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/596,958	06/20/2000	Jihyun Francis Kim	19603/3286(CRF D-2062B)	5427
7590	06/17/2002			
Michael L Goldman Esq Nixon Peabody LLP Clinton Square P O Box 31051 Rochester, NY 14603			EXAMINER	
			KUBELIK, ANNE R	
		ART UNIT	PAPER NUMBER	
		1638		12
		DATE MAILED: 06/17/2002		

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/596,958	KIM ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Anne Kubelik	1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_\_.  
 2a) This action is FINAL.                  2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-10 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_. is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_. is/are allowed.  
 6) Claim(s) 1-10 is/are rejected.  
 7) Claim(s) \_\_\_\_\_. is/are objected to.  
 8) Claim(s) \_\_\_\_\_. are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_. is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 11) The proposed drawing correction filed on \_\_\_\_\_. is: a) approved b) disapproved by the Examiner.  
 If approved, corrected drawings are required in reply to this Office action.  
 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
 \* See the attached detailed Office action for a list of the certified copies not received.  
 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
 a) The translation of the foreign language provisional application has been received.  
 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)            | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)   |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. . | 6) <input type="checkbox"/> Other: _____                                      |

**DETAILED ACTION**

1. The amendments to the specification, the cancellation of claims 11-16 and 29-37, and the amendment of claims 1-7 and 9-10 requested in paper No. 11, filed 1 April, 2002, have been entered. Claims 1-10 are pending.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. The drawings are objected to for the reasons indicated on the accompanying form PTO 948. Corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance. See 37 CFR 1.85(a) and MPEP 608.02(b).

***Claim Rejections - 35 USC § 112***

4. Claims 1 and 4-10 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for nucleic acids of SEQ ID NO:1 or encoding SEQ ID NO:2, does not reasonably provide enablement for nucleic acids that hybridize under conditions of unspecified stringency to SEQ ID NO:1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The rejection is repeated for the reasons of record as set forth in the last Office action mailed 19 December, 2001, as applied to claims 1-16 and 29-31.

Applicant's arguments filed 1 April, 2002, have been fully considered but they are not persuasive. Applicant urges that the claims have been amended to recite specific hybridization

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conditions. Applicant argues that HR can be tested by applying protein to the plant leaves, as described in Gopalan et al, included by Applicant. Applicant argues that HR elicitors share the characteristics of being glycine rich, heat stable, hydrophilic, a lacking cysteine, as cited in each of Bonas (1994-I), Bonas (1994-II), and Preston et al, included by Applicant. Applicant also states that SEQ ID NO:1 hybridized to many strains and species of *Erwinia*, as described in Example 10 and Figure 6 (response pg 5-7).

This is not found persuasive because hybridization time and wash conditions are not recited in the claims. Additionally, the references included in the response were not cited in the specification.

As stated in the prior Office action, expression of *hrp* genes in plants is unpredictable. As constitutive elicitor production can be lethal to a plant, producing disease resistance via transformation with a gene encoding an elicitor protein also requires a pathogen-induced promoter (Keller et al, 1999, Plant Cell 11:223-235, see pg 224, left column paragraph 1). This is illustrated by Bauer et al (1999, Acta Hort. 489:301-304), who showed that while *Arabidopsis* plants transformed with the *hrpN* gene expressed behind a pathogen-inducible promoter were resistant to downy mildew, those transformed with the *hrpN* gene expressed behind a constitutive promoter were not (pg 302, paragraphs 5-6). In fact, constitutive expression of *hrpN* in these latter plants resulted in physical damage to the plants (pg 302, paragraph 6). Bauer et al also showed that the *hrpN* construct must be expressed with a signal sequence for export of the protein from the plants cells for production of resistant plants to be successful (pg 302, paragraph 5). The instant specification fails to teach the necessity for inducible promoters or how lethality

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or plant damage can be prevented without them, and it fails to teach the need for signal sequences for protein export.

5. Claims 1 and 4-10 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is repeated for the reasons of record as set forth in the last Office action mailed 19 December, 2001, as applied to claims 1-16 and 29-31.

Applicant's arguments filed 1 April, 2002, have been fully considered but they are not persuasive. Applicant urges that SEQ ID NO:1 has been characterized as has the protein it encodes, and this protein shares the characteristics of other hypersensitive response elicitors. Applicant also argues that the nucleic acid of SEQ ID NO:1 hybridizes to nucleic acids in other *Erwinia* species and that a single species is representative of the claimed genus (response pg 7-8).

This is not found persuasive because hybridization times and wash conditions are not cited in the claims. Additionally, the function of the encoded protein, *i.e.*, the activity of the enzyme, is not recited.

See *In re Shokal*, 113 USPQ 283, (CCPA 1957) at pg 285

It appears to be well settled that a single species can rarely, if ever, afford sufficient support for a generic claim. *In re Soll*, 25 C.C.P.A. (Patents) 1309, 97 F.2d 623, 38 USPQ 189; *In re Wahlforss et al.*, 28 C.C.P.A. (Patents) 867, 117 F.2d 270, 48 USPQ 397. The decisions do not however fix any definite number of species which will establish completion of a generic invention and it seems evident therefrom that such number will vary, depending on the circumstances of particular cases. Thus, in the case of small genus such as the halogens, consisting of four species, a reduction to practice of three, or perhaps even two, might serve to complete the generic invention, while in the case of a genus comprising hundreds of species, a considerably larger number of reductions to practice would probably be necessary. ... We are of the opinion that a genus containing such a large number of species cannot properly be identified by the mere recitation or reduction to practice of four or five of them. As was pointed out by the examiner, four species might be held to support a genus, if such genus is disclosed in clear language; but where those species must be relied on not only to illustrate the genus but to define what it is, the situation is otherwise.

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6. Claims 1-10 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections. The rejection is repeated for the reasons of record as set forth in the last Office action mailed 19 December, 2001, as applied to claims 1-16 and 29-31.

Applicant's arguments filed 1 April, 2002, have been fully considered but they are not persuasive. Applicant urges that the rejections are traversed.

This is not found persuasive. Claims 1 and 4 are indefinite for their recitation of "a DNA molecule which hybridizes to a DNA molecule comprising a nucleotide sequence of SEQ ID No. 1 under conditions" in part (c). It is not clear if "under stringent conditions" is intended to modify "SEQ ID No:1", "sequence" or "hybridizes". The hybridization conditions are indefinite because hybridization time and wash conditions are not recited.

#### *Claim Rejections - 35 USC § 102*

7. Claims 1, 4-10 remain rejected under 35 U.S.C. 102(a) as being anticipated by Kim et al. The rejection is repeated for the reasons of record as set forth in the last Office action mailed 19 December, 2001, as applied to claims 1-10.

Applicant's arguments filed 1 April, 2002, have been fully considered but they are not persuasive. Applicant urges that Kim et al do not describe the sequence of the hrpW gene.

This is not found persuasive because the nucleic acid of Kim et al would hybridize to SEQ ID NO:1 in the conditions indicated in part (c) of claim 1, given that hybridization time and wash conditions are not recited.

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8. Claims 1 and 4-10 remain rejected under 35 U.S.C. 102(e) as being anticipated by Bauer et al. The rejection is repeated for the reasons of record as set forth in the last Office action mailed 19 December, 2001, as applied to claims 1-16 and 29-31.

Applicant's arguments filed 1 April, 2002, have been fully considered but they are not persuasive. Applicant urges that Bauer et al does not teach a nucleic acid as claimed in claim 1.

This is not found persuasive because the *hrpN<sub>Ech</sub>* gene taught by Bauer et al would hybridize to SEQ ID NO:1 under the hybridization conditions recited, given the lack or recitation of hybridization time or wash conditions.

9. Claims 1 and 4-10 remain rejected under 35 U.S.C. 102(b) as being anticipated by Wei et al (1992, Science 257:85-88). The rejection is repeated for the reasons of record as set forth in the last Office action mailed 19 December, 2001, as applied to claims 1-10.

Applicant's arguments filed 1 April, 2002, have been fully considered but they are not persuasive. Applicant urges that Wei does not teach a nucleic acid as claimed in claim 1.

This is not found persuasive because the *hrp* gene taught by Wei et al would hybridize to SEQ ID NO:1 under the hybridization conditions recited, given the lack or recitation of hybridization time or wash conditions.

#### *Claim Objections*

10. Claim 3 is objected to because there is an article missing before "protein" in line 2.

11. Claims 2-3 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form.

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*Conclusion*

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (703) 308-5059. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst, Kimberly Davis, at (703) 305-3015.

Anne R. Kubelik, Ph.D.

June 12, 2002

DAVID T. FOX  
PRIMARY EXAMINER  
GROUP 180 1638

